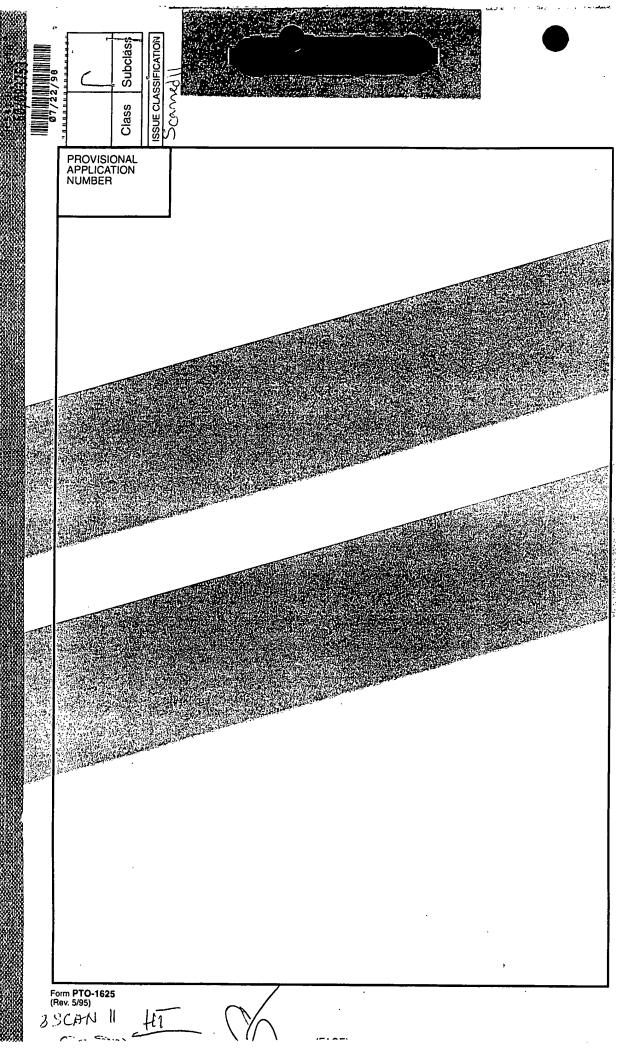
PEST AVAILABLE COPY



600	APPLICATION 93753			LAPPROVEDI INITIALIS	72.1984TS
entered & Counted Counted		CONTE	NTS		Date Received or Mailed
	1. Application	t for	papers.		8/ ₁ 2
	56 77				
A Company of the Comp	10 11				
	13 14 15 16				
	17 18 19 20				
	21 22 23 24				
	25 26 27 28				
	29 30 31				

SERIAL NUMBER		FILING DATE	CLASS	GRO	UP ART UNIT	ATTORNET DO	CKET NO.
60/093,75 PROVISION		07/22/98			0000	GOE3034.	02A
GERALD GOET LONGMONT, C	Z, PENN VA O; ANDREW	LLEY, CA; TERF FANTON, WESTMI	RY PRECHT, INSTER, CO;	LOVELAN BRIAN	ND, CO; BRIA HEPP, LONGM	N COPPOM, ONT, CO.	
CONTINUIN VERIFIED	G DOMESTIC	DATA*****	******	***			·
371 (NAT' VERIFIED	L STAGE) D	ATA******	******	.			
FOREIGN A	PPLICATION	S***			•		
VERIFIED							
		E GRANTED 08/2 lyes □no □Met after	-	TATE OR DUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
rified and Acknowle			(CA	5		
JOHN P O'B GERBER RIT 400 CAPITO SUITE 1550 SACRAMENTO	ANION CHEY AND C L MALL				,		
POCKET DOC	TOR						
FILING FEE RECEIVED \$150	No.	ority has been giv _ to charge/credit _ for the	DEPOSIT A	CCOUNT	1.17 Fe	es (Filing) es (Processing es (Issue)	Ext. of time)

.

PATENT	APPLICATION	SERIAL	NO.	

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FEE RECORD SHEET

07/28/1998 CHIHS1 00000049 60093753

01 FC:114

150.00 OP

PTO-1556 (5/87)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

EMARK OFFICE (1) CONTROL OF THE CONT

Box Provisional Patent Application Assistant Commissioner for Patents Washington, D.C. 20231

PROVISIONAL APPLICATION TRANSMITTAL

(37 CFR §1.51(2)(i))

Transmitted herewith for filing is:

1. Type of Application:

PROVISIONAL (37 CFR §1.51(a)(2)(i)(A))

2. Name and address of Inventor(s):

Gerald Goetz, Goetech L.L.C.,15304 Sisson Road, Penn Valley, CA 95946
Terry Precht, TDP, Inc. 4015 S. Lincoln Ave, Loveland, CO 80537
Brian Coppom, The Product Group, 1140-B Boston Avenue, Longmont, CO 80501
Andrew Fanton, Fanton Consulting, 14695 Pecos Street, Westminster, CO 80020
Brian Hepp, Quve L.L.C., 455 Weaver Park Road, Suite 100, Longmont, CO 80501

3. Title of Invention:

POCKET DOCTOR

CERTIFICATION UNDER 37 CFR 1.10

(Type or print name of person mailing

(Signature of person mailing paper)

NOTE: Each paper or fee referred to as enclosed herein has the number of the "Express Mail" label placed thereon prior to

mailing. 37 CFR 1.10(b).

Page '

. . ----

4.	Name,	registration and telephone number of attorney:			
		P. O'Banion, Reg. No. 33,201 498-1010			
	_	A power of attorney accompanies this transmittal			
5.	Corres	spondence Address:			
	GERB 400 Ca	P. O'Banion ER, RITCHEY & O'BANION LLP apitol Mall, Suite 1550 nento, CA 95814			
6.	This ir	ovention was made by an agency of the U.S. Government or under contract with an y of the U.S. Government			
	X	No.			
	_	Yes.			
		Name of U.S. Government agency and the Government contract number:			
		•			
7.	ldentif	ication of Application Documents Enclosed:			
	A.	Required by 37 CFR §§1.51(a)(2)(ii)-(iii)			
		13 Pages of Specification			
		5 Sheets of Drawings			
	В.	Additional Documents			
		1 Pages of Claims			
		1 Pages of Abstract			
8.	Langua	age			
	X	English			
	non-English				
		the attached translation is a verified translation 37 CFR 1 52(d)			

9.	Assig	nment						
	X	An assignment of the invention to: GOETECH L.L.C.						
		is attached. A separate "ASSIGNMENT COVER LETTER ACCOMPANYING NEW PATENT APPLICATION" is also attached.						
		X will follow.						
10.	Fee C	alculation (37 CFR 1.16)						
	Small	Entity Statement(s)						
	_	Verified Statements(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27						
		is(are) attached.						
		Filing Fee Calculation \$ 150.00						
11.	Fee F	ayment Being Made At This Time						
•••	_	Not Enclosed						
		No filing fee is to be paid at this time. (This and the surcharge required by 37 CFR						
		1.16(e) can/will be paid subsequently.)						
	Х.	Enclosed						
		X basic filing fee \$						
		recording assignment (\$40.00; 37 CFR 1.21(h)) \$						
		Total Fees Enclosed \$150.00						
12.	Meth	od of Payment of Fees						
	X	Check in the amount of \$ _150.00						
	_	Charge Account No in the amount of \$ A duplicate of this						
		transmittal is attached.						
13.	Inst	ructions As To Overpayment						
	_	credit Account No						
	Х.	refund						

14. Incorporation By Reference of Papers Identified Herein

Applicant(s) hereby incorporate(s) by reference all papers which are identified in this New Application Transmittal.

Dated:

SIGNATURE OF ATTORNEY

John P. O'Banion, Reg. No. 33,201 GERBER, RITCHEY & O'BANION LLP 400 Capitol Mall, Suite 1550 Sacramento, CA 95814 Telephone: (916) 498-1010

TITLE OF THE INVENTION

POCKET DOCTOR

CROSS-REFERENCE TO RELATED APPLICATIONS

Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

REFERENCE TO A MICROFICHE APPENDIX

Not Applicable

NOTICE OF MATERIAL SUBJECT TO COPYRIGHT PROTECTION

All of the material in this patent document is subject to copyright protection under the copyright laws of the United States and of other countries. The owner of the copyright rights has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure, as it appears in the United States Patent and Trademark Office file or records, but otherwise reserves all copyright rights whatsoever.

20

GOE3034.02A 1 EL032642010US

BACKGROUND OF THE INVENTION

Field of the Invention

This invention pertains to a patient controlled personal medical information product.

2. <u>Description of the Background Art</u>

Medical science has created many new methods, treatments, and medications to extend and improve the lives of people. However, this has resulted in a significant increase in the medical information that a person must be aware of in order to maintain their health, and get the best benefit from these medical improvements. For example, people over the age of 55 consume a daily average of 7 different prescription medications. Each medication requires specific instructions, including warnings on correct consumption and possible side effects. Because there is such a significant increase in the amount of medical information that a person must know, such as proper use and consumption of these medications, many errors can occur that result in the effect of treatments being counteracted or minimized. At worst, serious injury or death has occurred due to incorrect treatments. One estimate from data shows 28% of hospitalizations are a result of "adverse drug events" and this costs the health care industry \$76 billion annually (CU Doctor Sues Firm... Rocky Mountain News, June 8, 1998).

Problems arise when the person making the prescription, filling the prescription or consuming the prescription makes an error, or provides information that is not understood by one of the other parties in this "medical information loop." These errors

GOE3034.02A 2 EL032642010US

can be from transcription, misinterpretation, or insufficient information available. the most common patient errors are:

- (a) taking incorrect doses
- (b) taking doses at wrong time
- (c) forgetting to take a dose
- (d) stopping medication too soon
- (e) taking dosage improperly, causing interactions

To date, many solutions to help patients manage medications have been developed.

Generally these solutions fall into two categories:

Patient Based Products

The products are reminder pill boxes and auto dispensing mechanisms. They are difficult to program, configured for a very limited number of medications, and too cumbersome to be considered a portable personal device. In particular, they did not easily link into the medical information chain and allow the physician or pharmacist to interact with the patient, nor did they provide complete medical information.

Medical Organization Based Products

These products are database systems run by hospitals, health maintenance organizations (HMO's) or health insurance companies. They are systems tied to these large organizations, with significant computer hardware requirements and no portability. In particular, the patient has no ability to control or read information at their discretion.

GOE3034.02A

3

BRIEF SUMMARY OF THE INVENTION

For the patient to better control medication therapies a device is needed that will track and display:

- (a) medication name & purpose
- (b) dosage, frequency and duration
- (c) possible side effects
- (d) record of medications taken
- (e) special instructions for taking medications, such as with or without meals, fluids, avoiding sunlight, etc.

Besides information about medications, it is important for a patient to have a brief medical history that can be provided to health care providers, have a log of consumption for their medications, and maintain information about who their physicians, dentist, pharmacies, insurance providers are, and personal contact information. This data is considered critical not only during typical interaction with health care providers, but particularly in emergency medical situations. Any device that is capable of tracking the medication data a patient needs should also be capable of tracking all these other health related data.

However, it must be recognized that this medical information loop includes other personnel, as an example, physicians and pharmacists. Thus any device must be capable of allowing them to read patient data, and input information, and it must not require any significant time for them to accomplish this. In particular it must blend with day to day activities of the health care provider.

EL032642010US

GOE3034.02A 4

Any solution to the problem must recognize this medical information chain that primarily consists of the patient, the health care prescriber (typically the physician) and health care provider (for example, the pharmacist). The information in this chain is created on a per patient basis, making the patient the natural repository for the information, with the prescriber being the initiator of the information, and the provider being a source of complementary information so it is in a form useful to the patient. Thus the product must work with both medical terminology and layman's terms to promote optimum benefit of treatments and medications.

An additional requirement of any product that contains medical history information is security. Thus any product must provide maximum protection of data from access by unauthorized persons. Although many devices use PIN's to limit access and a PIN or password would be necessary for this product, the nature of the data in a device such as proposed here should also protect the data via encryption.

The present invention is a system of devices that provide proper information to the patient to get maximum benefit from their medications. It is capable of managing information, in a highly portable form for an individual patient. The invention will:

- (a) Record prescription information
- (b) Maintain personal medical data
- (c) Create historical log of consumption
- (d) Warn of side effects, interactions, and other special instructions

 Interchange data among various individuals and groups involved in patient care such as patient, physician, pharmacist, emergency medical personnel and hospital personnel.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:

Figure 1 is a functional system diagram of a Pocket Doctor system according to the present invention.

Figure 2 is a perspective view of a patient product portion of the Pocket Doctor system of the invention.

Figure 3 is a perspective view of an alternative embodiment of the patient product shown in Figure 2.

Figure 4 is a flow chart showing a method of viewing data on the patient products shown in Figure 2 and Figure 3.

Figure 5 is a flow chart showing a method of responding to an alarm from a patient product in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention comprises a system of products that share a common database, where the database is contained on a device known as a smart card (currently embodied as an integrated circuit or chip containing a microprocessor, ROM, RAM, and EEPROM, packaged within a plastic panel much like a credit card, but could be manifested in a variety of forms). The three products are:

20 Patient Product

This product provides for the following:

Displays the medical data contained in the smart card by reading the

GOE3034.02A

- 2. Allows the patient to scroll through the data using various means to indicate, via a typical graphical user interface menu, which type of data is to be displayed.
 - 3. Maintains date and time information.
- 4. Provides an alarm for when an event, such as required consumption of a medication, is to occur. The alarm can be visual, aural, or tactile.
- Indicate sdosage, frequency, special considerations in consuming the medication.
- 6. Assists in taking the correct medication by providing some means to identify the type of pill to be taken. The device will have sufficient intelligence and quality of display to actually show a graphic of the medication to be taken. (a red cylindrical pill, a blue heart shaped pill...)
- 7. Provides information about correct consumption of the medication, including possible interactions, side effects.
- 8. Provides a method to indicate the alarmed event was accepted or delayed, and log the time, date, and action for that alarm.
- 9. Provides power to perform the above functions, as the smart card will not contain any power of its own.
- 10. Is portable such that it can be maintained on the person at all times, such as in a pocket, purse, or worn with a strap on an arm, around the neck or waist. The device will also provide various means to attach to highly visible surfaces, such as a

magnet or hook and loop fabric.

11. Allows security, via coding features and data encryption, to prevent unauthorized use.

Physician Product

This product provides for the following:

- Displays the medical data contained in the smart card by reading the EEPROM on the smart card.
- Contains data specific to the physician, such as a list of medications to be prescribed, and special instructions or treatments to be performed by the patient.
 Write data to the patient's smart card.
- Has a special enclosure for use in areas where blood born pathogens are a concern (emergency rooms, surgical areas).

Pharmacist Product

Nearly all pharmacists now have a personal computer in the pharmacy, with links to various health organizations, in particular organizations that provide data on both prescription and OTC medications. There is a code, known as the National Drug Code (NDC) that identifies every medication sold in the US. In combination with this code and the access to various databases, the pharmacist can supply necessary information about the prescribed medication to the patient. At this time, this data is printed on a sheet (typically 5.5" by 8") that contains common uses, consumption requirements, cautions and possible side effects. Thus the pharmacist only needs a device to read and write data to the smart card, and would supply the data that is currently printed on

GOE3034.02A 8 EL032642010US

the prescription information sheet.

To assist the pharmacist in properly preparing data for the patient, a software application will be provided that correctly formats the data in a form useable to the patient. This software application will reside on the same PC that the pharmacist currently has. It is important that the time and effort for the pharmacist to provide this medication data to the patient in this new product be very minimal, typically 15 seconds or less.

The diagram in Figure 1 shows the smart card as the link between three possible points of information in the medical information loop. Each point in the loop has a device that is capable of accessing the medical data on the smart card. The proposed invention uses smart card technology to make the link between the three to be easy, quick, and secure. The devices could also communicate via infrared serial communication links, or other communication methods such as the recently developed Personal Area Network (PAN).

Currently, there is existing hardware on the market to satisfy the requirements for the pharmacist and physician, plus smart cards are in general use, to the point that the mechanical and electrical interface requirements have been standardized by International Standards Organization (ISO).

However, the data contained on the smart card, the use of a patient device to provide the identified capability, and the type of data that is maintained on the smart card is unique. The smart card will contain the following data about the patient:

5

1	Pat	ion	+ 1	r
ı	 rai	len	1 1	L

- 1.1 name, address, phones
- 1.2 age, weight
- 2. Contact Information
 - 2.1 names, phones, relationship
- 3. Doctors
 - 3.1 physicians & affiliation, such as internist, dentist, optometrist
 - 3.2 all phone numbers and addresses
- 4. Insurance Information
 - 4.1 Company, plan
 - 4.2 contact phone
- 5. Medication Consumption History Log
 - 5.1 Date & time for each medication consumed
 - 5.2 Date & time for a delayed medication
 - 5.3 Occurrence of any side effect from a medication
- 6. Medical Conditions
 - 6.1 brief history
 - 6.2 allergies
 - 6.2 current conditions
 - 6.4 relevant family history
- 7. Prescription data (for every medication consumed)
 - 7.1 name (trade/ generic) indication

GOE3034.02A

10

- 7.2 dosage, frequency, timing
- 7.3 interactions
- 7.4 side effects
- 7.5 special instructions
- 7.6 prescribing physician
- 7.7 dispensing pharmacy & date
- 8. Other information
 - 8.1 Advertising messages for product sponsors
 - 8.2 Special instructions for emergency personnel

Two sample configurations of the patient device are shown in Figures 2 and 3. The system allows a variety of devices to be used, but each one must have the capabilities to perform the prescribed unique functions. In the case of Figure 2, the device has a slot to accept the smart card, and only requires 3 buttons to access to the data, or to respond to the event alarm. Figure 3 shows a device, much like a woman's compact, that contains a larger display area, such that elderly with reduced visual acuity can still use such a product. All proposed embodiments use the smart card as the memory storage device, displays information concerning proper consumption of medications, warnings concerning interactions or side effects and steps for prescribed treatments, plus interaction to indicate response to alarmed events indicating when medications are consumed.

Any of the possible emobodiments share the same basic configuration:

1. A smart card containing personal medical information as defined

11

5

previously.

- Display devices that will allow the medical information contained on the smart card to be shown to the person using that device and provide a visual alarm indicator.
- 3. A simplified input method, using either a minimum number of buttons, such as 3 or less, or using a rotating knob to select a particular item on the screen, and then a push button to select that item so that more information about that item can be displayed.
- 4. An audio section for the alarm that includes a speaker and possibly voice modules for output or input.
- 5. The smart card can contain specific identifying information, such as names, photo ID, special medical symbols to indicate its function, and location to send if found by persons other than the owner. A bar code on the card, with a unique patient ID that could include such things as the person's blood type, which would allow immediate data for emergency personnel.

The block diagram for any such device is typical for a microprocessor-controlled product with a LCD display.

Both of the sample patient devices use the 3 button input configuration to display data and to respond to alarms. A possible algorithm for viewing the data on the device is shown in Figure 4. This basic algorithm would access the data contained on the smart card.

To respond to an alarm, a possible sequence of steps for the patient unit is

12

shown in Figure 5.

The integration of the smart card with this appropriate medical data can also be applied to devices that dispense the medication. Other medical assistance devices for special needs such as hearing or sight impaired are also possible.

Although the description above contains many specificities, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention.

GOE3034.02A 13 EL032642010US

CLAIMS

What is claimed is:

- A personal medical information database, contained on a portable data storage medium, that can be read by hand held personal information devices. One type of portable data storage medium is a "smart card" device.
- 2. A personal medical information device that uses the data on the portable data storage medium to provide information to a patient that guides and protects the patient in treatment application, particularly but not limited to, consumption of both prescription and over the counter medications. The protection includes alarms to warn when to take medications, with the option of delaying until later. If a delay is requested, the device will determine if the delay will result in improper consumption of the medication, and redefine conditions as to when would be the correct time and conditions to take the medication. The device also displays cautions, warnings, and lists side effects from any medication to be consumed.
- A device, and method to interact with retail medication providers
 (pharmacists) that allows data to be transferred to the portable data storage medium.
- A device and method to interact with the health care provider
 (physician) that allows them to review and input data relevant to the patient's treatments and prescriptions.
- 5. A system of devices, as defined above, that allow the patient, the health care provider, and the retail medication provider to fully interact and exchange data about the patients particular treatment and medication requirements.

GOE3034.02A

14

ABSTRACT OF THE DISCLOSURE

A system of devices that provide proper information to a patient to get maximum benefit from medications. The system is capable of managing information, in a highly portable form for an individual patient, and can (a) record prescription information; (b) maintain personal medical data; (c) create historical log of consumption; and (d) warn of side effects, interactions, and other special instructions Interchange data among various individuals and groups involved in patient care such as patient, physician, pharmacist, emergency medical personnel and hospital personnel.

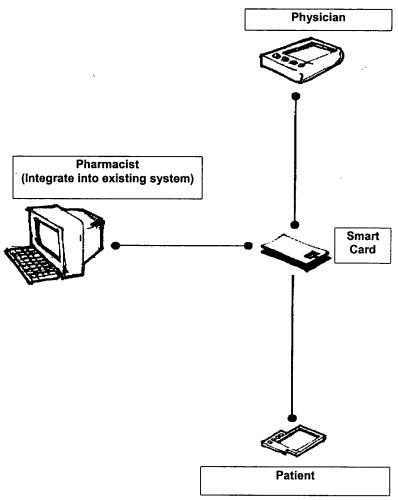
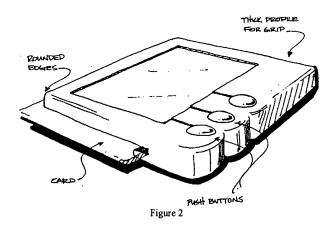
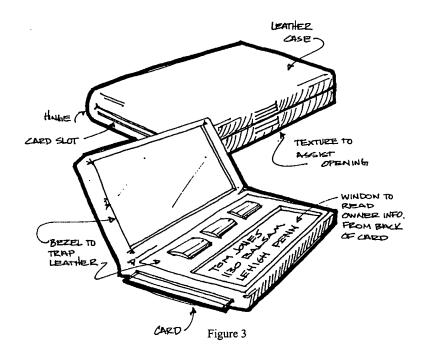


Figure 1





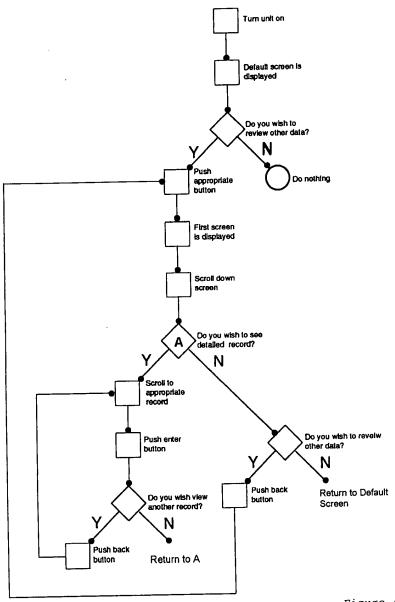


Figure 4

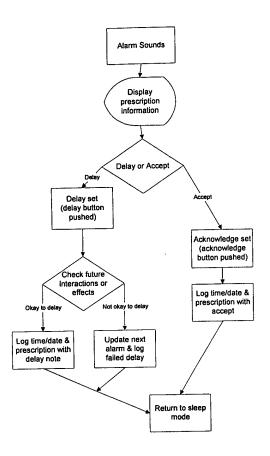


Figure 5

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defect	ts in the images include but are not limited to the items checked:
4 1	BLACK BORDERS
_ D I	IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
ψ,	FADED TEXT OR DRAWING
7	BLURRED OR ILLEGIBLE TEXT OR DRAWING
. D s	SKEWED/SLANTED IMAGES
	COLOR OR BLACK AND WHITE PHOTOGRAPHS
	GRAY SCALE DOCUMENTS
 I	LINES OR MARKS ON ORIGINAL DOCUMENT
	REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
П	OTHED.

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.